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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,490	12/11/2000	Roger Desmond Drinkwater	13922	6804

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Gardner City, NY 11530

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,490	<b>Applicant(s)</b> DRINKWATER ET AL.	
	<b>Examiner</b> Gabriele E. BUGAISKY	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 17-20 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 5-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1103</u> | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment of October 2003 is acknowledged. Claims 10-13 remain withdrawn from consideration, claims 15-16 have been cancelled, rendering any rejections of these claims as moot., and new claim 20 has been submitted. Claims currently under consideration are 1-9, 14, and 17-20.

### ***Information Disclosure Statement***

Reference AA on the PTO 1449 has been crossed out, as it is already of record. A reference may only be considered once.

### ***Specification***

The objection to the specification is withdrawn, based upon the amendment.

### ***Claim Objections***

The objection to claim 19 is withdrawn, based upon the amendment.

Claims 4-6 remain objected to because of the following informalities: they recite non-elected subject matter. With respect to claim 4, only the peptide of SEQ ID NO:2 is directed to elected subject matter. Applicants' remarks on page 13 are noted :

It is observed that claims 4-6 ultimately depend on claim 1 and are drawn to  $\omega$ -conotoxin peptides characterized by certain specified sequences including SEQ ID NO: 5 (claims 5-6), or certain specified sequences in the second loop of the peptide (claim 4). Although Applicants have elected SEQ ID NO: 5 as the peptide species for continued prosecution, SEQ ID NO: 5 and other peptides encompassed by claims 4-6 are all related to each other as isolated synthetic or recombinant ( $\omega$ -conotoxin peptides,

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which share the same features as delineated in claim 1, e.g., having the fourth loop sequence as set out in SEQ ID NO: 1. Applicants respectfully submit that, because the generic claim (i.e., claim 1) is patentable (as further submitted hereinbelow), Applicants should not be required to restrict the claims to only SEQ ID NO: 5. Therefore, withdrawal of the objection to claims 4-6 is respectfully requested.

The Examiner has only searched generic SEQ ID NO:1 and SEQ ID NO:5. If Applicants wish to state on the record that the non-elected peptides are not patentably distinct from SEQ ID NO 5, then there is no search burden and the restriction requirement for the individual peptides will be withdrawn.

***Claim Rejections - 35 USC § 101***

The rejection of claims 9 and 19 under 35 U.S.C. 101 for non-statutory subject matter is withdrawn, based upon the amendment.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 remain rejected and claims 8, 14, 17-20 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the especially disclosed peptides of SEQ ID NOs: 5-7, 14-31 and  $\omega$  conotoxins that bind to calcium channels and contain the subsequences SEQ ID NOs:1-2, does not reasonably provide enablement for

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any  $\omega$  conotoxins comprising 1 or more conservative amino acids or side chain modifications of SEQ ID NO 1, or for methods of use of any such compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Due to a typographical error in the previous Action, claims 1-5 were rejected under this statute; the rejection of claim 5 is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 9 and 19 under 35 U.S.C. 112, second paragraph, for recitation of a use and recitation of VSVV is withdrawn, based upon the amendment.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-9, 14 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Justice *et al.* (US patent 5364842) The reference provides for the use of  $\omega$ - conotoxins including TVIA, SNX-207 and SNX-236 in blocking N type calcium channels (see Example I, induction of analgesia (Example 7, and in screening methods for compounds which bind to

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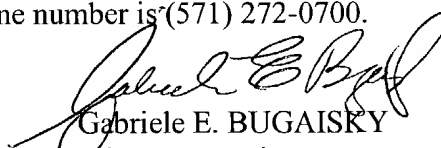
calcium channels (Example 3) The reference is deemed anticipatory for the claimed subject matter because each of these  $\omega$ - conotoxins contains in the 4<sup>th</sup> loop between cysteine residues 5 and 6, a hexapeptide sequence which by substitution is derived from SEQ ID NO:1. Each of these has been used in binding assays and in pharmaceutical treatment which thus anticipate the instantly recited treatments of claims 17-18 and assays of claims 9 and 19.

The rejection of claims 1-4 , 8-9, 14 and 17-19 under 35 U.S.C. 102(b) as being anticipated by Miljanich *et al.*. (US patent 5424218) is withdrawn, upon further consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0700.

  
Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

3/20/2004